

PDUFA
FDA and Stakeholders Public Meeting
September 15, 2000
Agenda

9:00 am **Welcome** Mark Barnett, Moderator

9:10 am **Opening Remarks** Jane Henney, M.D.

**9:20 am –
10:00 am**

Panel I - Presentations by FDA

- Linda Suydam, D.P.A.
Senior Associate Commissioner, FDA
- Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research, FDA
- Kathy Zoon, Ph.D.
Director, Center for Biologics Evaluation and Research, FDA

**10:00 am –
11:00 am**

Panel II - Presentations by Patient Advocacy Groups

- Abbey Meyers
President, The National Organization for Rare Disorders
- Jeff Bloom
Patient Representative
- Carl Dixon
Executive Director, Kidney Cancer Association
- Myrl Weinberg, CAE
President, National Health Council

**11:00 am –
11:15 am**

Break

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**11:15 am –
12:15 pm**

Panel III - Presentations by Consumer Protection Groups

- Cindy Pearson
Executive Director, National Women's Health Network
- Larry Sasich, Pharm.D., M.P.H., FASHP
Pharmacist, Public Citizen
- Brett Kay
Program Associate, National Consumer League
- Arthur Levin, M.P.H.
Director, Center for Medical Consumers

**12:15 pm –
1:30 pm**

Lunch

**1:30 pm –
2:30 pm**

Panel IV - Presentations by Industry Groups

- Larry Versteegh, Ph.D.
Vice President, Procter and Gamble Pharmaceuticals
- Carl Feldbaum
President, Biotechnology Industry Organization
- Christopher Pelloni
Vice President of Research and Development, TEVA
Pharmaceuticals USA
- Robert Milanese
President, National Association of Pharmaceutical
Manufacturers

**2:30 pm –
2:40 pm**

Break

**2:40 pm –
3:40 pm**

**Panel V - Presentations by Health Professional Groups and
Academic Research**

- Joe Cranston, Ph.D.
Director of Science, Research and Technology, American
Medical Association

- John Gans, Pharm.D.
Executive Vice President, American Pharmaceutical
Association
- Richard Levinson, M.D., D.P.A.
Associate Executive Director, American Public Health
Association
- Kenneth Kaitin, Ph.D.
Director, Tufts Center for the Study of Drug Development
- Stuart Walker
Director, Centre for Medicines Research International

3:40 pm

Open Public Comment Period